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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,159	06/24/2003	Nebojsa Janjic	NEX66/D2	3567

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SWANSON & BRATSCHUN, L.L.C.
8210 SOUTHPARK TERRACE
LITTLETON, CO 80120

EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
01/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efspatents@sbiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/606,159	JANJIC ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8 and 10-15* is/are pending in the application.

4a) Of the above claim(s) *1-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be to directed to Brian Whiteman, Art Unit 1635.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/28/09 has been entered.

Election/Restrictions

Claims 1-6 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/16/06.

Priority

The relationship in the cross-reference on page 1 of the instant specification between the present application and application no. 08/479,725 is required. From the application data sheet of record it is appears that the instant application is a CIP of '725.

US Patent No. 6,592,918 on line 2 should be US Patent No. 6,582,918. Application 08/991,743 is now US Patent No. 6,229,002.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/479,783 and 08/479,725, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Instant claims 8 and 10-15 do not appear to have written support in applications no. '783 and 725 because the limitations "SEQ ID NO: 146" and "PDGF" are not disclosed in these applications. Thus, the instant claims appear to only enjoy priority to application no. 08/618,693 filed on 3/20/96

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8 and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 15, 26, 27, and 34 of U.S. Patent No. 6,582,918 in view of Gold et al. (US 5,270,163, of record) and Griffin et al. (US 5,756,291).

Instant claim 8 is directed to a method of targeting a therapeutic or diagnostic agent to a location expressing PDGF in a patient comprising the steps of covalently linking a therapeutic or diagnostic agents to a complex comprising the PDGF nucleic acid ligand of SEQ ID NO: 146 and a non-immunogenic, high molecular weight compound or lipophilic compound to form a complex and administering the complex to a

patient. Claim 10 recites the use of the 5' 40K PEG described above, wherein the target is not a tumor.

Claim 12 of the '918 patent is directed to a method of inhibiting the growth of tumors expressing PDGF by forming a complex of a PDGF nucleic acid ligand with a non-immunogenic, high molecular weight compound or lipophilic compound to form a complex and administering said complex to a patient. When performing this method, one of ordinary skill in the art would look to the working examples of the '918 patent for guidance regarding suitable nucleic acid ligands targeting PDGF and would find that the patent teaches that SEQ ID NO: 146 conjugated with 5' 40K PEG is efficacious in inhibiting restenosis and treating glomerulonephritis.

While claim 12 of the '918 patent does not teach combining the nucleic acid ligand complex with a therapeutic agent, wherein the target is not a tumor, one of ordinary skill in the art would it obvious to do so because Gold et al. (of record) teach that nucleic acid ligands can be used as a drug delivery vehicle and one of ordinary skill in the art recognize (see Griffin, columns 4-5) that therapies routinely involve combinations of therapeutic agents. In addition, one of ordinary skill in the art understands at the time of filing, that expression of PDGF is associated with disorders or diseases other than a tumor. Based on these teachings, one of ordinary skill in the art would have reason to link the agent to the nucleic acid ligand complex of claim 12 in order to use a nucleic acid ligand in the manner suggested by Gold et al. Thus claims 8 and 10 are an obvious variation of claim 12 of the '918 patent in view of the teachings of Gold et al. and Griffin.

Applicant's arguments, see pages 5-7, filed 12/28/09, with respect to the rejection(s) of claim(s) 8 and 10 under double patenting have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Griffin.

Claims 8, 10, 11, 12, 13, and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 15, 26, 27, and 34 of Janjic et al. (U.S. Patent No. 6,582,918) in view of Gold et al. (US 5,270,163, of record) and Griffin et al. (US 5,756,291) in further view of Gold et al. (US 6,011,020).

Claim 12 of the '918 patent is directed to a method of inhibiting the growth of tumors expressing PDGF by forming a complex of a PDGF nucleic acid ligand with a non-immunogenic, high molecular weight compound or lipophilic compound to form a complex and administering said complex to a patient. When performing this method, one of ordinary skill in the art would look to the working examples of the '918 patent for guidance regarding suitable nucleic acid ligands targeting PDGF and would find that the patent teaches that SEQ ID NO: 146 conjugated with 5' 40K PEG is efficacious in inhibiting restenosis and treating glomerulonephritis.

While claim 12 of the '918 patent does not teach combining the nucleic acid ligand complex with another nucleic acid ligand, wherein the target is not a tumor, one of ordinary skill in the art would it obvious to do so because Gold et al. (of record) teach that nucleic acid ligands can be used as a drug delivery vehicle and one of ordinary skill in the art recognize (see Griffin, columns 4-5) that therapies routinely involve

combinations of therapeutic agents. In addition, one of ordinary skill in the art understands at the time of filing, that expression of PDGF is associated with disorders or diseases other than a tumor. Based on these teachings, one of ordinary skill in the art would have reason to link the agent to the nucleic acid ligand complex of claim 12 in order to use a nucleic acid ligand in the manner suggested by Gold et al. Thus claims 8 and 10 are an obvious variation of claim 12 of the '918 patent in view of the teachings of Gold et al. and Griffin.

Furthermore, at the time the invention was made, Gold et al. (US 6,011,020) claim attaching an additional therapeutic or diagnostic agent to a complex comprising a nucleic acid ligand and PEG and using it in a method (claims 14 and 22-24).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the claims of Janjic, the teaching of Gold and Griffin and the claims of Gold (US 6,011,020), namely to produce the complex recited in the instant claims and use it in the claimed method. One of ordinary skill in the art would have been motivated to combine to treat or diagnose a disorder associated with expression of PDGF. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." See ***KSR v. Teleflex***, 550 U.S. ___, 127 S. Ct. 1727 (2007).

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 12-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 15, 26, 27, and 34 of Janjic et al. (U.S. Patent No. 6,582,918) in view of Gold et al. (US 5,270,163, of record) and Griffin et al. (US 5,756,291) and Gold et al. (US 6,011,020) in further view of Gold et al. (US 5,811,533).

Claim 12 of the '918 patent is directed to a method of inhibiting the growth of tumors expressing PDGF by forming a complex of a PDGF nucleic acid ligand with a non-immunogenic, high molecular weight compound or lipophilic compound to form a complex and administering said complex to a patient. When performing this method, one of ordinary skill in the art would look to the working examples of the '918 patent for guidance regarding suitable nucleic acid ligands targeting PDGF and would find that the patent teaches that SEQ ID NO: 146 conjugated with 5' 40K PEG is efficacious in inhibiting restenosis and treating glomerulonephritis.

While claim 12 of the '918 patent does not teach combining the PDGF nucleic acid ligand complex with a VEGF nucleic acid ligand, one of ordinary skill in the art would it obvious to do so because Gold et al. (of record) teach that nucleic acid ligands can be used as a drug delivery vehicle and one of ordinary skill in the art recognize (see Griffin, columns 4-5) that therapies routinely involve combinations of therapeutic agents. In addition, one of ordinary skill in the art understands at the time of filing, that expression of PDGF is associated with disorders or diseases other than a tumor. Based on these teachings, one of ordinary skill in the art would have reason to link the

agent to the nucleic acid ligand complex of claim 12 in order to use a nucleic acid ligand in the manner suggested by Gold et al.

Furthermore, at the time the invention was made, Gold et al. (US 6,011,020) claim attaching an additional therapeutic or diagnostic agent to a complex comprising a nucleic acid ligand and PEG and using it in a method (claims 14 and 22-24).

In addition, at the time the invention was made, Gold et al. (US 5,811,533) claim a VEGF nucleic acid ligand (claims 1-18).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the claims of Janjic, the teaching of Gold and Griffin and the claims of Gold (US 6,011,020) in further view Gold et al. (US 5,811,533), namely to produce the complex recited in the instant claims and use it in the claimed method. One of ordinary skill in the art would have been motivated to combine to treat or diagnose a disorder (e.g., restenosis) associated with expression of PDGF and VEGF.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant is advised that should claims 11 be found allowable, claim 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number 571-272-0764. The examiner can normally be reached on from 6:30 to 4:00 (Eastern Standard Time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor Tracy Vivlemore can be reached on 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Brian Whiteman/
Primary Examiner, Art Unit 1635